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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/215,482	03/17/2014	Terrence J. Hunt	17319 CP3C1DV1DV1CON2 BOT	4989

51957 7590 07/11/2017

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ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
07/11/2017	ELECTRONIC

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte TERRENCE J. HUNT[1]
(Applicant: Allergan, Inc.)

Appeal 2017-006993
Application 14/215,482
Technology Center 1600

Before ERIC B. GRIMES, RICHARD J. SMITH, and DAVID COTTA, *Administrative Patent Judges*.

SMITH, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a multi-component system for making a botulinum toxin formulation. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

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[1] According to Appellant, the real party in interest is Allergan, Inc. (Br. 3.)

STATEMENT OF THE CASE

Claims on Appeal

Claims 6–8 are on appeal. (Claims Appendix, Br. 16.) Claim 6 is illustrative and reads as follows:

> 6. A multi-component system for making a botulinum toxin formulation, comprising: (a) a vacuum-dried or lyophilized botulinum toxin; and (b) a reconstitution vehicle comprising an albumin, hydroxyethyl starch, sodium chloride, a buffer, or combinations thereof; wherein the vacuum-dried or lyophilized botulinum toxin is reconstituted with the reconstitution vehicle at the time of use.

Examiner's Rejections

1. Claims 6–8 stand rejected under 35 U.S.C. § 101 as directed to non-statutory subject matter (i.e., a product of nature). (Final Act. 2–15.)[2]

2. Claims 6–8 stand provisionally rejected on the ground of nonstatutory double patenting over claims 6–9 of copending Application No. 13/933,723. (Final Act. 15–16.)

FINDINGS OF FACT

FF 1. The Examiner finds that Johnson et al (US 5,512,547, issued April 30, 1996) ("Johnson") "discloses pharmaceutical compositions comprising botulinum toxin and human serum albumin [], both components hav[e] their natural structure and therefore are natural products." (Final Act. 3, citing Johnson cols. 1–2.)

FF 2. The Examiner finds that Goodnough et al. (*Stabilization of Botulinum Toxin Type A during Lyophilization*, Applied and Environmental

[2] Office Action dated April 14, 2016 ("Final Act.").

Microbiology 58 (10), 3426–28 (1992)) ("Goodnough") teaches that "full recovery of type A botulinum toxin can be obtained after lyophilization, therefore indicating that the structure is the same as the natural product as well as function. . . . [t]he structure and function is not markedly different from what exists in nature." (Final Act. 3–4, citing Goodnough Abstract and 3426.)

FF 3. The Examiner finds that "[b]ased on the state of the art, the instant product claim recites something that appears to be a natural product that is not markedly different in structure and function from naturally occurring products. There is no structural difference because each of the components of the claimed invention is not markedly different." (Final Act. 4.)

FF 4. The Specification states that

> a multiple (i.e. two or more) component system for the making of a final formulation can provide the benefit of allowing incorporation of ingredients which are not sufficiently compatible for long-term shelf storage with the first component of the two component system or which for other reasons it is not desirable to include with the first component of the pharmaceutical composition.

(Spec. 69, ll. 13–18.)

FF 5. The Specification states that '"[b]otulinum toxin' means a neurotoxin produced by Clostridium botulinum, as well as a botulinum toxin (or the light chain or the heavy chain thereof) made recombinantly by a non-Clostridial species." (*Id.* at 30, ll. 30–32.)

DISCUSSION

Rejection No. 1

Issue

Whether a preponderance of evidence of record supports the Examiner's rejection of claims 6–8 under 35 U.S.C. § 101.

Principles of Law

On issues of patent eligibility, we "first determine whether the claims at issue are directed to a patent-ineligible concept," such as laws of nature, natural phenomena, and abstract ideas. *Alice Corp. Pty Ltd. v. CLS Bank Int'l*, 134 S.Ct. 2347, 2355 (2014) ("*Alice*"). If this threshold is met, we move to the second step of the inquiry and "consider the elements of each claim both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application." *Id.* (quoting *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S.Ct. 1289, 1297–98 (2012) ("*Mayo*")).

Analysis

We adopt the Examiner's findings and conclusion that the claims are directed to patent-ineligible subject matter. (Final Act. 2–16; Ans. 2–9.) We discern no error in the rejection of the claims under Section 101. We limit our consideration to claim 6 because the claims were not separately argued.

Claim Construction

Claims under examination are given their broadest reasonable interpretation consistent with the specification, as interpreted by one of

ordinary skill in the art. *In re Am. Academy of Sci. Tech Center*, 367 F.3d 1359, 1364 (Fed. Cir. 2004). Here, we agree with the Examiner that claim 6 recites two components, a vacuum-dried or lyophilized botulinum toxin and a reconstitution vehicle (e.g., albumin). (Final Act. 14.) Moreover, claim 6 does not require that the components be mixed or interact in any way. (*Id.*) As stated by the Examiner, "[t]he claim is so broad it reads on the two components sitting in separate vials, in a box." (*Id.*)

This construction of separate components is consistent with the Specification's description of a multi-component system. (FF 4.) Moreover, the "wherein" clause at the end of claim 6 indicates that the components are separate, and that the purpose of the separate components is to be "reconstituted . . . at the time of use." (Br. 16.) Accordingly, that "wherein" clause does not change the scope of the claim from two separate components to a mixture or composition of the components, but merely states the context in which the two separate components may be used. *See Boehringer Ingelheim Vetmedica v. Schering-Plough Corp.*, 320 F.3d 1339, 1345 (Fed. Cir. 2003) ("An intended use or purpose usually will not limit the scope of the claim because such statements usually do no more than define a context in which the invention operates.").

Alice Inquiry – Step 1

The Examiner finds that claim 6 "is directed to a judicial exception (i.e., a law of nature, a natural phenomenon, or an abstract idea) without significantly more." (Final Act. 2.) In particular, the Examiner finds that claim 6 is directed to a "product of nature" exception because neither the

lyophilized (or vacuum-dried) botulinum toxin nor albumin exhibit markedly different characteristics than found in nature. (*Id.* at 2–5; FF 1–3.)

Appellant does not dispute that the individual components (i.e. vacuum-dried or lyophilized botulinum toxin and albumin) of claim 6 are nature-based products.[3] However, Appellant asserts two arguments which are addressed below.

Argument 1

Appellant argues that "it is not necessary to apply the markedly different characteristics analysis" because "the claim is focused on the assembly of components that together form the claimed system and not the nature-based products." (Br. 10.) Appellant supports that argument by referencing the Interim Eligibility Guidance (December 2014) ("Interim Guidance") and Nature-Based Product Examples (December 2014) ("Examples").[4] Appellant specifically points to a hypothetical claim to a fountain-style firework in which the claim is identified as patent eligible because "[a]lthough the claim recites two nature-based products (calcium chloride and gunpowder), analysis of the claim as a whole indicates that the claim is focused on the assembly of components that together form the firework, and not the nature-based products." (Br. 10, citing Examples at 1 (claim 2).)

[3] We focus our decision on "albumin" as the reconstitution vehicle.
[4] Links to both the Interim Guidance and Examples may be found at https://www.uspto.gov/patent/laws-and-regulations/examination-policy/subject-matter-eligibility.

We are not persuaded. The firework claim argued by Appellant also recites a cardboard body having different compartments for the calcium chloride and gunpowder, as well as other elements, such as a plastic ignition fuse extending out of the cardboard body. (Br. 10, Examples at 1.) Here, unlike the firework claim, claim 6 merely recites two natural components that may be contained in separate vials or other containers that are not "assembled" or otherwise connected in any manner. (*See* Ans. 5–6.)

Argument 2

Appellant also argues that "the claimed pharmaceutical composition is markedly different from its naturally occurring components" because, for example, "whether the albumin is natural or recombinant, the albumin stabilizes the botulinum toxin." (Br. 10–13.) Thus, according to Appellant, "the changed property [e.g., enhanced stability] between botulin toxin as a part of the claimed composition and botulinum toxin in nature is a marked difference." (*Id.* at 13.)

Appellant supports that argument by reference to certain Examples regarding composition claims. (Br. 10–13.) One of those claims is "[a] beverage composition comprising pomelo juice and an effective amount of an added preservative" in which "the preservative affects the juice so that it spoils much more slowly." (Br. 10–11, citing Examples at 2 (claim 2).) The analysis of that claim indicates that the property of slower spoiling of the combination "is markedly different from properties of the juice by itself in nature." (Br. 11, Examples at 2, emphasis by Appellant.) The other claim referred to by Appellant is to "[a] stable aqueous composition comprising: amazonic acid; and a solubilizing agent," in which the solubility property

"between amazonic acid as a part of the claimed stable aqueous composition and amazonic acid in nature is a marked difference." (Br. 10–11, citing Examples at 3–5 (claim 6), emphasis by Appellant.)

We are not persuaded. Claim 6 on appeal is not directed to a composition, and the components (as claimed) are not required to be combined or mixed. (*See* discussion above.) As such, the structural and functional characteristics of the components are the same (i.e., not markedly different than found in nature). (*See* Ans. 6–7.) Accordingly, we find that claim 6 is directed to a patent-ineligible product of nature.

Alice Inquiry – Step 2

Appellant does not specifically argue the second step of the *Alice* framework.[5] Moreover, we agree with the Examiner's analysis that the claim as a whole does not amount to "significantly more than the judicial exception." (Ans. 7–9.) Thus, for example, even if the Appellant's separate components are part of a kit, that would be insufficient to provide the inventive concept necessary to render the claims patent eligible, or otherwise transform the nature of the claim into a patent-eligible application. *See Mayo,*132 S.Ct. at 1297; *see also Genetic Technologies Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1375–77 (Fed. Cir. 2016). Accordingly, the rejection of claim 6 under 35 U.S.C. § 101 is affirmed.

[5] All of the Examples argued by Appellant state that the hypothetical claims are not directed to a "product of nature" exception (*Alice* Step 1). (*See* Examples at 1–5.) Furthermore, Appellant concludes the arguments by stating that claim 6 "is not directed to an exception [], and qualifies as eligible subject matter." (Br. 13.)

Conclusion

A preponderance of evidence of record supports the Examiner's rejection of claim 6 under 35 U.S.C. § 101. Claims 7 and 8 were not argued separately and fall with claim 6.

Rejection No. 2

Appellant does not contest the provisional double patenting rejection. Accordingly, the rejection of claims 6–8 on the ground of nonstatutory double patenting over claims 6–9 of copending Application No. 13/933,723, is summarily affirmed. *See Hyatt v. Dudas*, 551 F.3d 1307, 1314 (Fed. Cir. 2008).

SUMMARY

We affirm the rejection of claims 6–8 under 35 U.S.C. § 101.

We affirm the rejection of claims 6–8 on the ground of provisional nonstatutory double patenting.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED